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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LUONG, PETER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,972	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> Peter Luong	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 45 is objected to because of the following informalities: the preamble recites "a connector in combination with an intrabody guidewire or medical coaxial cable" however the claim body on recites structure relating to the connector, it is unclear whether the intrabody guidewire/medical cable is actively claimed and if so, the claim body omits structural elements relating to the guidewire/cable. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed fails to disclose the combination of a guidewire comprising a connector. The specification discloses a guidewire for insertion into connectors and connectors designed to receive coaxial cables. Therefore, the specification fails to disclose the claimed combination of a MRI guidewire comprising a connector and guidewire. With respect to claims 23, 30, and 37-38, the specification as originally filed fails to disclose wherein the guidewire,

connector, or guidewire and connector combination comprises an identification parameter. Page 28 of the specification discloses only the connector comprises an identification parameter. With respect to claim 25, the specification as originally filed fails to disclose wherein the inner conductor contact and the inner conductor define a diameter that is greater than a diameter of the inner conductor.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23 and 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claims 23 and 37, the limitation of "and/or" renders the scope of the claim indefinite.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 9-29, 31, 33-36, and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Lardo et al. (US 6,675,033).

10. With respect to claims 1-4, 9-12, 16-23, 25-29, 31, 33-36, and 39-45, the patent of McKinnon discloses a MRI guidewire (abstract) comprising an inner conductor (13, i.e. center conductor), an outer conductor (15), a distal end sized and shaped for insertion into a subject to receive MRI signals (fig 1), a proximal end sized and shaped for insertion into a connector (col. 4, lines 54-65; see fig 1, it is inherent for a connection means to connect the guidewire to the control station), an insulated area between the outer and inner conductor (14), and the guidewire is connected to the MRI scanner and MRI circuits (fig. 1). With respect to the inner and outer conductor contacts, the Examiner interprets the surface of the inner and outer conductors to be the contacts as any conductive material touching the surface of the conductor would be electrically coupled to the conductor. McKinnon discloses the inner conductor extending beyond the outer conductor (col. 4, ln. 57-65). (col. 4, line 66 to col. 5, line 27; figs. 1-3). With respect to claim 16, the Examiner notes that any material can be made sterilizable. With respect to claim 22, McKinnon discloses an extension attachment at the proximal end of the guidewire (col. 5, ln. 7-9). With respect to claim 25, it is obvious to one of ordinary skill in the art to change the size of the diameter of the inner/outer conductors

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and contacts as the change in size is well within the skill level of one of ordinary skill in the art. With respect to claim 38, the Examiner notes that any device can be disposed of after a single-use.

11. McKinnon does not teach a connector, however, Lardo et al. teaches MRI guidewires releasably attachable to connectors. Lardo et al. teaches wherein all the components are non-magnetic (col. 14, lines 57-58). Lardo et al. teaches various sizes and shapes of the connectors (see figures). Lardo et al. teaches an interfacing circuit (fig. 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided McKinnon with connectors as taught by Lardo et al. in order facilitate connecting to interface circuitry to be connected to the MRI scanner (col. 11, lines 4-6).

12. With respect to claims 13-15, the patent of McKinnon discloses the subject matter substantially as claimed except for wherein the guidewire comprises titanium or nitinol.

13. However, Lardo et al. teaches a MRI guidewire probe comprising known super-elastic material comprising titanium and nitinol (col. 9, lines 25-50).

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the super-elastic material as taught by Lardo et al. those materials are known for their high biocompatibility (col. 9, lines 32-35).

15. With respect to claim 24, McKinnon discloses the subject matter substantially as claimed except for wherein the connector includes a wiper to inhibit the introduction of fluids into the connector. However, it is obvious to one of ordinary skill in the art to

provide the connections between the guidewire and electronic circuitry with seals to prevent fluid contact as the intended use of a guidewire is to be inserted into a patient.

16. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Lardo et al. (US 6,675,033) as applied to claim 1, further in view of Glowinski et al. (US 5,868,674).

17. The patent of McKinnon discloses the subject matter substantially as claimed except for wherein the guidewire diameter is between about 0.012 inches and 0.038 inches and an inner conductor diameter to be between about 0.004 inches and about 0.012 inches.

18. However, Glowinski et al. teaches a MRI catheter with a diameter between 0.3 mm (0.0118 inches) to 3 mm (0.118 inches) for insertion into a patient (fig. 1).

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the guidewire diameter to be about 0.012 inches and 0.038 inches as a change in size is within the skill level of one of ordinary skill in the art. Furthermore, it would have been obvious for the inner conductor to be smaller than the guidewire.

20. Claims 23, 30, 32, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Lardo et al. (US 6,675,033) as applied to claims 1 and 25, further in view of Wiener et al. (US 7,273,483).

21. McKinnon discloses the subject matter substantially as claimed except for a guidewire sensor. However, Wiener et al. teaches in medical devices in which comprises releasable components for handpiece, blades, and shears to have unique

identification numbers registered and stored in memory. Wiener et al. teaches the ID allows the system to acknowledge their compatibility and usability of each individual piece. (col. 13, lines 24-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided McKinnon with the unique ID system of Wiener et al. in order to allow the system to acknowledge the compatibility and useability of each component of guidewire and connector.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-45 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571)270-1609. The examiner can normally be reached on Monday - Friday, 9:30 a.m. - 6:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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